UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LINDA EVANGELISTA,	:	Civil Action No. 1:21-cv-7889
Plaintiff,	:	
-against-	:	**DEFENDANT ZELTIQ AESTHETICS, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS**
ZELTIQ AESTHETICS, INC.,	:	
Defendant.	:	

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INTRODUCTION

While plaintiff brings claims under many legal theories, this is effectively a product liability case, for which plaintiff seeks $50 million. The product at issue is an FDA-cleared class II medical device called the CoolSculpting System. The CoolSculpting System, manufactured and sold by Zeltiq, is FDA-cleared for the treatment of visible fat bulges in various parts of the body. It uses controlled cooling to target and freeze (thereby killing) fat cells under a patient's skin (the medical term is cryolipolysis), and the body then naturally removes those dead fat cells.

Before plaintiff received her first CoolSculpting treatment, she was warned of the very risk about which she now complains. Plaintiff alleges she suffered paradoxical adipose hyperplasia ("PAH"), which she describes as an adverse effect that occurs when fat cells treated by CoolSculpting "actually grow larger, . . . [and which] requires invasive, corrective liposuction surgery to remove." The crux of her allegations is that she and her physician were not warned of this risk and that the lack of warning caused her injury. But plaintiff also pleads she signed an informed consent form, which specifically warned her of this exact risk and makes clear she understood and accepted the risk:

> I understand and accept that possible risks and complications include but are not limited to the following . . . known potential side effects . . .
>
> It is also unlikely but there is a small possibility of ***fat growing instead of going away***. There are a very small number of reports of [this] but [it] ***may require surgical correction***.
>
> * * *
>
> I have been fully explained this procedure by Dr. Grossman. Although favorable results are expected, no guaranties [sic] or warranties of any kind, either express or implied, have been made . . . .
>
> I also understand that, although unusual, an unexpected complication or less than desirable result can occur, which may result in the need for further treatments(s) [sic], additional tests, prolonged recovery, loss of work time and the possibility of further expense to me. (emphasis added).

Plaintiff not only signed the informed consent, she also initialed it in the exact location warning of PAH and other possible risks.

It is not mere happenstance that plaintiff's physician warned plaintiff about the risk of PAH from CoolSculpting treatment; indeed, the Amended Complaint establishes that Zeltiq warned her physician of this very risk. In the CoolSculpting System User Manual that plaintiff references in her Amended Complaint, Zeltiq expressly warned physicians, including plaintiff's physician, of the rare but real risk of fat cells growing following treatment and that the condition could require surgery to correct:

> Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.[1]

Plaintiff ignores this warning in seeking to hold Zeltiq liable for failing to warn her physician.

Plaintiff also attempts to state claims against Zeltiq for allegedly failing to warn her—rather than her physician—about the risk of developing PAH following CoolSculpting treatment. But the CoolSculpting System is by law a prescription-only medical device. For such devices, New York law is clear: Zeltiq's duty to warn runs to the physician only, not to the patient. If that were not enough, the FDA specifically exempted Zeltiq from any duty to warn lay patients, like plaintiff, about the risks associated with the CoolSculpting System: "As a prescription device, under 21 C.F.R. 801.109, ***the device is exempt from having adequate directions for lay use***." (emphasis added).

[1] Plaintiff's Amended Complaint refers to the condition of fat cells growing following treatment as paradoxical adipose hyperplasia (PAH). *E.g.*, Am. Compl. ¶¶ 37–48, 96, 142. Zeltiq has consistently referred to this rare adverse event as PH, including in its User Manuals. Nevertheless, because Plaintiff's Amended Complaint refers to the condition as PAH, Zeltiq does the same for purposes of this motion.

Because Zeltiq was under no obligation to warn plaintiff directly, and because the Amended Complaint demonstrates that Zeltiq satisfied its obligation to warn her physician, plaintiff's failure-to-warn claims fail.

Plaintiff's claims warrant dismissal for additional reasons. Her express-warranty claim fails at nearly every turn. It fails because vague and indefinite statements like those plaintiff claims are warranties (such as "safe and effective") are not actionable warranties at all. It fails because the pleaded facts do not support that those non-warranty statements were inaccurate. And it fails because the pleaded facts do not support that she or her physician relied on those statements or that they caused her injury.

Plaintiff's fraud-based claims fail because she has not alleged which supposed misstatements she or her physician saw or relied upon.

Her consumer-protection claims under N.Y. Gen. Bus. Laws §§ 349 and 350 fail because (1) providing medical warnings about a prescription-only device is not consumer-oriented conduct, (2) plaintiff has not alleged any deceptive or misleading act, and (3) plaintiff has not properly alleged causation.

Moreover, plaintiff pleads facts in the Amended Complaint that make all her claims—except promissory estoppel—untimely. She pleads that the CoolSculpting System that allegedly injured her was sold by Zeltiq no later than August 2015 and that she was injured by it no later than June 2016. She filed her original Complaint in September 2021. This renders time-barred her failure to warn, design defect, and negligence claims (three-year limitations period); fraud-based claims that are incidental to her personal injury claims (three-year limitations period); consumer-protection claims (three-year limitations period); and warranty claims (four-year limitations period).

The Court should dismiss plaintiff's claims as set out above and below.

LEGAL STANDARD

Under Rule 12(b)(6), the Court "accept[s] as true all material factual allegations in the complaint and draw[s] all reasonable inferences in the plaintiff's favor." *Rusis v. Int'l Bus. Machines Corp.*, 529 F. Supp. 3d 178, 190 (S.D.N.Y. 2021) (citing *Johnson v. Rowley*, 569 F.3d 40, 43 (2d Cir. 2009)). "The complaint 'must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Id.* (quoting *Johnson*, 569 F.3d at 44). Plausibility requires more than recitals of causes of action; it requires well-pleaded facts showing that the plaintiff is entitled to relief. *Id.* (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). As the Supreme Court has held, "[a] pleading that offers 'labels and conclusions' or a 'formulaic recitation of the elements of a cause of action will not do.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. 544, 555 (2007)). And "while a court must generally accept a plaintiff's factual allegations as true in evaluating a motion to dismiss, it need not accept as true allegations in a complaint that contradict or are inconsistent with judicially-noticed facts." *Becker v. Cephalon, Inc.*, No. 14 Civ. 3864(NSR), 2015 WL 5472311, at *5 (S.D.N.Y. Sept. 15, 2015) (cleaned up).

ARGUMENT

I. Ten of plaintiff's claims (counts 1 through 10) are time-barred.

The timeliness of claims "is a threshold issue." *Hirsch v. Suffolk Cnty.*, No. 08-CV-2660(JS)(AKT), 2015 WL 1275461, at *7 (E.D.N.Y. Mar. 18, 2015) (citing *Valdez ex rel. Donely v. United States*, 518 F.3d 173, 181 (2d Cir. 2008)). And "[a] statute of limitations defense may be decided on a Rule 12(b)(6) motion if the defense appears on the face of the complaint." *Wei Su v. Sotheby's, Inc.*, No. 17-CV-4577 (VEC), 2019 WL 4917609, at *2 (S.D.N.Y. Oct. 4, 2019) (quoting *Ellul v. Congregation of Christian Bros.*, 774 F.3d 791, 798

n.12 (2d Cir. 2014)). "An allegation of time or place is material when testing the sufficiency of a pleading." Fed. R. Civ. P. 9(f). On the face of the Amended Complaint, counts 1 through 10 are time-barred.

A. Plaintiff's claims for failure to warn (count 1), design defect (count 2), and negligence (count 3) are barred by New York's three-year statute of limitations.

Under N.Y.C.P.L.R. § 214(5), "an action to recover damages for a personal injury" must be commenced within three years. The statute begins to run from the date of injury, rather than the date of discovery of the injury. *See, e.g.*, *Barrell v. Glen Oaks Village Owners, Inc.*, 29 A.D.3d 612, 613 (N.Y. App. Div. 2006) ("As a general rule a cause of action for personal injuries, whether sounding in negligence, malpractice, or products liability, accrues at the time of injury." (internal quotation marks omitted)).

As pleaded, plaintiff's claims for failure to warn (count 1), design defect (count 2), and negligence (count 3) are time-barred. She pleads that "within a few months" of her final CoolSculpting treatment in February 2016, she "developed hard, bulging, painful masses under her skin in those areas of her body treated with ZELTIQ's CoolSculpting System." Am. Compl. ¶ 95. She pleads that she was diagnosed with PAH in June 2016. *Id.* ¶ 96. Construing the allegations most favorably to plaintiff, Zeltiq uses the last day in June 2016 as the trigger date for the statute of limitations—June 30, 2016. Three years from June 30, 2016, was June 30, 2019. Plaintiff did not file her original Complaint (ECF No. 1) until September 21, 2021, more than two years too late. These claims should be dismissed as time-barred.[2]

[2] Zeltiq notes that there are unpleaded factors relating to the statute of limitations issues, such as tolling agreements between the parties. Since Zeltiq must take the Amended Complaint as plaintiff pleads it under Rule 12(b)(6), it does not address those unpleaded factors above. *See Thea v. Kleinhandler*, 807 F.3d 492, 501 (2d Cir. 2015) ("When a plaintiff relies on a theory of equitable estoppel to save a claim that otherwise appears untimely on its face, the plaintiff must specifically plead facts that make entitlement to estoppel plausible (not merely possible)."). If

B. Plaintiff's fraud-based claims (counts 6 through 9) are barred by the three-year statute of limitations.

Under New York law, common-law fraud claims are generally subject to a six-year statute of limitations. *See* N.Y.C.P.L.R. § 213(8). But "[w]hen a fraud claim is incidental to another asserted claim, the claim does not sound in fraud for purposes of taking advantage of the longer limitations period." *Corcoran v. N.Y. Power Authority*, 202 F.3d 530, 545 (2d Cir. 1999); *Fisher v. APP Pharms., LLC*, 783 F. Supp. 2d 424, 429 (S.D.N.Y. 2011). Fraud claims are not incidental to a personal injury claim "only when (1) the fraud occurred separately from and subsequent to the injury forming the basis of the alternate claim; and (2) the injuries caused by the fraud are distinct from the injuries caused by an alternate claim." *Corcoran*, 202 F.3d at 545. Here, plaintiff's fraud claims are incidental to her personal injury claims.

First, plaintiff's fraud claims are based on the same conduct as her failure-to-warn product liability claims. *Compare* Am. Compl. ¶ 137 (failure to warn (count 1): alleging that Zeltiq failed to warn about "the actual incidence and occurrence of PAH" and "deemphasized the actual risk"), *with id.* ¶ 246 (fraudulent misrepresentation (count 6): failed to "disclose known health risks, including the true risk of PAH and the actual incidence and occurrence of PAH following treatment"), *and id.* ¶ 269 ("fraudulent concealment (count 7): failed to warn "of the true risk of PAH and the actual incidence and occurrence of PAH"), *and id.* ¶ 282 (negligent misrepresentation (count 8): "concealed material information" concerning "the risk of PAH" and "the actual incidence and occurrence of PAH"), *and id.* ¶ 312 ("fraud and deceit (count 9): "willfully and intentionally failed to disclose material facts" about "the true risk of PAH" and the "actual incidence and occurrence of PAH").

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plaintiff is allowed to file a third complaint after her current one is dismissed to address those tolling agreements, Zeltiq will show why her claims remain untimely.

Second, the injury allegedly caused by the fraud is the same injury caused by Zeltiq's alleged failure to warn. *Compare id.* ¶ 147 (failure to warn (count 1): "Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of . . . ZELTIQ's failure to warn"), *with id.* ¶ 256 (fraudulent misrepresentation (count 6): "Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein."), *and id.* ¶ 274 (fraudulent concealment (count 7): same), *and id.* ¶ 289 (negligent misrepresentation (count 8): same), *and id.* ¶ 321 (fraud and deceit (count 9): same).

On facts like these, courts routinely apply New York law to impose a three-year limitations period on fraud-based claims that are incidental to a personal-injury, failure-to-warn claim. *See, e.g.*, *Trisvan v. Heyman*, 305 F. Supp. 3d 381, 397 (E.D.N.Y. 2018); *Fisher*, 783 F. Supp. 2d at 429; *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 434 (W.D.N.Y. 2001).

Plaintiff's fraud-based claims are incidental to her failure-to-warn claims. As such, they are subject to the same three-year statute of limitations as the negligence and strict liability-based claims discussed in Section I.A., above. For the same reasons, her fraud-based claims in counts 6 through 9 should be dismissed as untimely.

C. Plaintiff's claims under N.Y. Gen. Bus. Law §§ 349 and 350 (count 10) are barred by a three-year statute of limitations.

Plaintiff's claims under N.Y. Gen. Bus. Law §§ 349 and 350 (count 10) should be dismissed as time-barred. Claims under both statutes are governed by a three-year statute of limitations. *See* N.Y.C.P.L.R. § 214(2); *Corsello v. Verizon New York, Inc.*, 967 N.E.2d 1177, 1184 (N.Y. 2012). The three-year limitations period begins to run when the plaintiff is injured by the allegedly deceptive conduct. *See Gaidon v. Guardian Life Ins. Co. of Am.*, 750 N.E.2d 1078, 1083 (N.Y. 2001). As shown above, plaintiff pleads that she was injured more than five

years before she filed her original Complaint. Plaintiff's claims under both sections of the N.Y. Gen. Bus. Law should be dismissed.

D. Plaintiff's express and implied warranty claims (counts 4 and 5) are barred by New York's four-year statute of limitations.

Plaintiff's claims for express warranty (count 4) and implied warranty (count 5) should also be dismissed as time-barred. New York applies the UCC's four-year statute of limitations to warranty claims. *See* N.Y. U.C.C. § 2-725. That four-year period begins to run "at the time the product is placed in the stream of commerce or at the time of the original sale of the good by the manufacturer, regardless of when the injury was sustained." *Hanlon v. Gilatech, Inc.*, No. CV-07-1737, 2008 WL 4773430, at *4 (E.D.N.Y. Oct. 27, 2008); *see also Heller v. U.S. Suzuki Motor Corp.*, 477 N.E.2d 434, 436 (N.Y. 1985) ("[I]t remains the law that a cause of action against a manufacturer or distributor accrues on the date the party charged tenders delivery of the product, not on the date that some third party sells it to plaintiff.").

Plaintiff pleads that she had her first CoolSculpting treatment on August 8, 2015. Am. Compl. ¶ 85. Construing the allegations most favorably to plaintiff, this means Zeltiq sold her physician's CoolSculpting System—and thus the warranty limitations period began to run—no later than August 8, 2015. Four years from August 8, 2015, is August 8, 2019. Plaintiff filed her original Complaint on September 21, 2021, more than two years too late. Plaintiff's express and implied warranty claims, therefore, should be dismissed.

II. Counts 1 and 3 through 10 fail because Zeltiq's duty to warn ran to plaintiff's physician, whom Zeltiq warned about PAH.

As part of her claims premised on failure to warn, plaintiff pleads that Zeltiq failed to adequately warn her and other "consumers" about the risks associated with CoolSculpting. New York has adopted the learned intermediary doctrine, which provides that for a prescription medical product like the CoolSculpting System that can be administered or dispensed only by a

healthcare provider, "the manufacturer's duty, under New York law, is to warn the medical community, not the patient of the product's risk." *Mulhall v. Hannafin*, 45 A.D.3d 55, 58 (N.Y. App. Div. 2007) (internal citation omitted); *see Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 151 (S.D.N.Y. 2012) ("The basis for this rule is that the doctor acts as an informed intermediary between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available [treatments], and prescribing and supervising their use." (internal quotation marks omitted)).[3]

Plaintiff's claims for negligence (count 3), breach of express warranty (count 4), breach of implied warranty (count 5), fraudulent misrepresentation (count 6), fraudulent concealment (count 7), negligent misrepresentation (count 8), fraud and deceit (count 9), and violation of N.Y. Gen. Bus. Laws §§ 349 and 350 (count 10) are simply repackaged versions of her failure-to-warn claim (count 1).[4] Accordingly, under New York law, the learned intermediary doctrine applies

[3] The physician, in turn, has a duty to "disclose to the patient such alternatives [to the treatment] and the reasonably foreseeable risks and benefits involved as a reasonable medical . . . practitioner under similar circumstances would have disclosed." N.Y. Pub. Health Law § 2805-d(1).

[4] *See* Am. Compl. ¶ 137 (failure to warn: "ZELTIQ knew of the risk of PAH associated with use of its CoolSculpting System but failed to adequately warn providers and/or consumers and intentionally omitted and/or concealed material information about the actual incidence and occurrence of PAH . . . ."); *id.* ¶ 184 (negligence: "ZELTIQ breached that duty by failing to adequately warn providers and/or consumers . . . of the true risk of PAH . . . ."); *id.* ¶ 220 (express warranty: "ZELTIQ . . . failed to adequately [warn of] all known risks of the serious risk of developing PAH following treatment . . . ."); *id.* ¶ 233 (implied warranty: "ZELTIQ's representations and warranties were false, misleading, and inaccurate in that ZELTIQ's CoolSculpting System posed a serious risk of adverse effects, including, but not limited to, PAH . . . ."); *id.* ¶ 251 (fraudulent misrepresentation: "ZELTIQ . . . failed to warn providers and/or consumers of all known serious adverse effects, including, but not limited to, PAH . . . ."); *id.* ¶ 270 (fraudulent concealment: "ZELTIQ fraudulently concealed and intentionally omitted material information . . . including, but not limited to, the true risk of PAH . . . ."); *id.* ¶ 281 (negligent misrepresentation: "ZELTIQ failed to exercise ordinary care and discharge its duty to warn by failing to warn providers and/or consumers . . . about the true risk of PAH . . . ."); *id.* ¶ 312 (fraud and deceit: "ZELTIQ willfully and intentionally failed to disclose material facts . . . including the true risk of PAH . . . ."); *id.* ¶ 336 (N.Y. Gen. Bus. Law: "ZELTIQ violated New

to each of these claims. *See Zottola v. Eisai Inc.*, -- F. Supp. 3d --, No. 20-CV-02600 (PMH), 2021 WL 4460563, at *6 (S.D.N.Y. Sept. 29, 2021) (dismissing claims for implied warranty of merchantability, fraud, fraudulent concealment, and unjust enrichment where those claims were "based on Plaintiff's allegations that Defendants misled consumers by concealing the cancer risks associated with the Medications").

A. Plaintiff cannot state a claim based on Zeltiq's alleged failure to provide medical warnings to her.

Under New York's learned intermediary doctrine, "[w]hen the product at issue is a medical device, the manufacturer's duty to warn applies to the physician as a 'learned intermediary' rather than to the patient" herself. *Tears v. Bos. Sci. Corp.*, 344 F. Supp. 3d 500, 511 (S.D.N.Y. Sept. 29, 2018) (citing *Banker v. Hoehn*, 718 N.Y.S.2d 438, 440 (2000)); *see Tomaselli v. Zimmer Inc.*, No. 14-CV-04474, 2017 WL 2820065, at *4 (S.D.N.Y. Jan. 20, 2017) ("For medical devices that require a prescription . . . the duty to warn runs to the prescribing physician, not the patient."), *report and rec. adopted*, 2017 WL 1011492 (S.D.N.Y. Mar. 15, 2017); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 183 (N.D.N.Y. 2014) ("[T]he manufacturer of a medical device does not have a duty to directly warn a patient of risks associated with the device, but instead discharges its duty by providing the physician with sufficient information concerning the risks of the device." (quoting *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999))).

The learned intermediary doctrine applies to any claim that Zeltiq failed to warn plaintiff about the risk of PAH, no matter how plaintiff frames that claim. *See Zottola v. Eisai Inc.*, 2021 WL 4460563, at *6; *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 696–97 (W.D.N.Y. 2017)

York consumer protection statutes, GBL §§ 349 and 350, by failing to disclose the true risk of PAH . . . .").

(holding that plaintiff's claims for negligence, negligent misrepresentation, strict liability, and breach of implied warranty "rise or fall upon the adequacy of defendants' warnings" to the learned intermediary); *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 410–11 (S.D.N.Y. 2014) (holding that a finding of adequacy on a failure-to-warn claim barred repackaged claims of design defect, negligence, breach of implied warranty, negligent misrepresentation, fraud, and violation of consumer-protection laws: "Relating a warning theory in terms of 'warranty' or 'fraud' does not avoid the implications of an adequate warning."); *Saavedra v. Eli Lilly and Co.*, No. 2:12-cv-9366, 2013 WL 3148923, at *3–4 (C.D. Cal. June 13, 2013) (holding that learned intermediary doctrine applies to N.Y. Gen. Bus. Law claims).[5]

The CoolSculpting System is an FDA-cleared class II medical device, Am. Compl. ¶ 11, and CoolSculpting treatments are available only through a healthcare provider. Ex. 1, FDA, Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use at 7 (Feb. 7, 2011), https://www.fda.gov/media/79881/download (emphasis added);[6] 21 C.F.R. § 878.4340(b) (adopting Special Controls); Ex. 2, User Manual at 3 ("Rx ONLY In the United States of America, Federal law restricts this device to sale by or on the order of a physician"); *id.* at 4 ("The system is intended for use by a trained physician or a physician-designated medical professional."); *Cates v. Zeltiq Aesthetics, Inc.*, 535

[5] *See also In re Norplant Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) ("The gravamen of all Plaintiffs' causes of action, including misrepresentation and violation of the [trade-practices act], is that [the manufacturer] failed to adequately warn of or disclose the severity of Norplant's side effects. Therefore, the learned intermediary doctrine applies to all of Plaintiffs' causes of action. . . . If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such as violation of the [trade-practices act] or a claim for misrepresentation, then the doctrine would be rendered meaningless.").

[6] The Court may take judicial notice of records on the FDA's website when considering a motion to dismiss. *See, e.g., Simon v. Smith & Nephew*, 990 F. Supp. 2d 395, 401 n.2 (S.D.N.Y. 2013); *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008).

F. Supp. 3d 1222, 1226 (M.D. Fla. 2021) ("CoolSculpting is a prescription medical device available only through a licensed healthcare practitioner, so the learned intermediary doctrine applies."), *appeal filed*, No. 21-12085 (11th Cir. Apr. 19, 2021). Indeed, as plaintiff pleads, she had to request treatment with the CoolSculpting System from her dermatologist, Dr. Grossman. Am. Compl. ¶ 73. Dr. Grossman, the physician licensed to perform plaintiff's CoolSculpting treatment, is the learned intermediary to whom Zeltiq owed a duty to warn; there is no duty to warn plaintiff under New York law. *See Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 893 (E.D.N.Y. 2018) ("[T]o the extent Plaintiff's failure to warn claim is premised upon Defendant's alleged failure to warn 'consumers' of the potential risks of complications associated with the use of the [device], such a claim is not viable in the first instance.").

Plaintiff does not plead that any exception to the learned intermediary doctrine exists. But even if she plans to rely on an unpleaded exception based on the CoolSculpting direct-to-consumer advertising she references in the Amended Complaint, New York—like the overwhelming majority of states—recognizes no such exception. *See DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 613–16 (S.D.N.Y. 2012) (refusing to find exception to learned intermediary doctrine where plaintiff alleged "extensive marketing in the public domain").[7]

Zeltiq's duty to warn ran to plaintiff's physician, not to plaintiff herself. Thus, the Court should dismiss plaintiff's warnings-based claims (counts 1 and 3 through 10) to the extent they rely on Zeltiq's alleged failure to adequately warn plaintiff, rather than her physician.

[7] *See also, e.g.*, *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1363, 1375–77 (S.D. Fla. 2007) (concluding that the Florida Supreme Court likely would not recognize a direct-to-consumer marketing exception to the learned intermediary doctrine); *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 950–51 (Ariz. 2016) (refusing to adopt direct-to-consumer advertising exception to the learned intermediary doctrine); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 162 (Tex. 2012) (declining to apply a direct-to-consumer exception).

B. Plaintiff's attempt to impose a New York state law duty to warn patients directly is also preempted by federal law.

Although the Court need not reach this additional issue (because the learned intermediary doctrine applies under New York law), any attempt by plaintiff to impose a duty on Zeltiq to warn her directly as a CoolSculpting patient would be preempted by federal law. *See Allstate Ins. Co. v. Serio*, 261 F.3d 143, 150 (2d Cir. 2001) ("[W]here possible, courts will render decisions on federal constitutional questions unnecessary by resolving cases on the basis of state law."). For FDA-cleared medical devices like the CoolSculpting System, Congress has expressly preempted any state-law requirement, such as a tort law duty, if that requirement is "different from, or in addition to," any federal requirement, and which "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). Here, any state law requirement on Zeltiq to warn plaintiff directly about CoolSculpting risks is expressly preempted.

In clearing the CoolSculpting System for cryolipolysis, the FDA issued device-specific regulations—"Special Controls," which "when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of" the CoolSculpting System. Ex. 1, FDA Special Controls at 1; *see* 21 C.F.R. § 878.4340(b) (establishing guidance as the Special Controls for CoolSculpting by federal regulation). Those Special Controls mandate that CoolSculpting is available by prescription only and that "[a]s a prescription device, under 21 C.F.R. 801.109, the device ***is exempt from having adequate directions for lay use***." Ex. 1, FDA Special Controls at 7 (emphasis added); *see* 21 C.F.R. § 801.109 (providing general labeling requirements for medical devices like the CoolSculpting System that are "not safe except under the supervision of a practitioner licensed by law to direct the use of such device"). In its notice adopting the Special Controls, the FDA acknowledged their preemptive force: "The special controls established by this final rule create 'requirements' to address each identified risk

to health presented by these specific medical devices under 21 U.S.C. 360k [(the preemption provision)], even though the product sponsors have flexibility in how they meet those requirements." 76 Fed. Reg. 6551-01, 6553 (Feb. 7, 2011).

Thus, although the learned intermediary doctrine clearly applies here (obviating any need to address federal preemption), the imposition of a duty to warn lay patients like plaintiff directly of the risks associated with CoolSculpting under New York law would also be preempted as a state-law requirement that is "different from, or in addition to" a federal requirement.

The Court should dismiss plaintiff's claims based on any duty by Zeltiq to warn her directly of the risks of the prescription-only CoolSculpting System.

C. Plaintiff's pleaded facts show that Zeltiq warned her physician about the risk of PAH and that it could require surgery.

Plaintiff asserts that Zeltiq failed to adequately warn her physician about "the actual risk of PAH associated with use of . . . CoolSculpting[,]" "the actual incidence and occurrence of PAH following CoolSculpting" and "the fact that invasive surgery is required to treat PAH." *E.g.*, Am. Compl. ¶ 137. Plaintiff asserts that these failures to warn caused her injury. *E.g.*, *id.* ¶¶ 147, 149. But plaintiff's allegations repeatedly reference Zeltiq's User Manual, in which Zeltiq expressly warned physicians of these very risks. *Id.* ¶¶ 269, 305–07, 313, 333; *see Dunham v. Covidien LP*, No. 19 Civ. 2851 (LLS), 2019 WL 6341179, at *4 (S.D.N.Y. Nov. 27, 2019) (holding that because medical-device manufacturer's instructions for use "is the very document that gives doctors the warnings that the [complaint] claims were insufficient, it is integral to the [complaint]" and should be considered).[8] This fact must be taken as true over

[8] The User Manual is repeatedly referenced in the Amended Complaint and is integral to Plaintiff's claims that Zeltiq failed to warn physicians of the risk of PAH. *See* Am. Compl. ¶¶ 269, 305–307, 313, 333. Accordingly, the Court may consider the User Manual. *See Twombly*, 550 U.S. at 568 n.13 (citing Fed. R. Evid. 201).

plaintiff's conclusory assertions to the contrary. *See 2002 Lawrence R. Buchalter Alaska Trust v. Phila. Fin. Life Aussur. Co.*, 96 F. Supp. 3d 182, 199 (S.D.N.Y. 2015) (noting that where documents referenced in the complaint "contradict the allegations of a plaintiff's complaint, the documents control and the court need not accept as true the allegations in the complaint" (internal quotation marks omitted)). The Court should dismiss plaintiff's claims that Zeltiq failed to warn plaintiff's physician of the risk of PAH and that it could require surgery to correct.

The User Manual warned physicians who were considering treating their patients with CoolSculpting that one of the "Rare Side Effects" experienced with CoolSculpting is PAH:

> Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.

Ex. 2, User Manual at 4. Zeltiq's User Manual thus expressly warned of the risk of PAH associated with CoolSculpting and the fact that surgery may be required. *See Dunham v. Covidien LP*, 498 F. Supp. 3d 549, 560 (S.D.N.Y. 2020) (granting motion to dismiss where "[t]he warnings given noted the risks of the complications that [plaintiff] actually experienced"). Indeed, whether from this explicit warning given by Zeltiq or from another source (for causation purposes, it does not matter which), plaintiff's physician was plainly aware of these risks because she incorporated the same warnings into her informed consent document that plaintiff acknowledges she understood and signed:

> It is also unlikely but there is a small possibility of fat growing instead of going away. There are a very small number of reports of [this] but [it] may require surgical correction.

Ex. 3, Informed Consent at 000015.[9] Based on these plain facts expressly pleaded or incorporated into plaintiff's Amended Complaint, her claim that Zeltiq failed to warn her

[9] Trial courts are "entitled to take notice of the full contents of the [material] referenced in the complaint, from which . . . truncated quotations [are] drawn." *Twombly*, 550 U.S. at 568

physician of the risk of PAH associated with CoolSculpting or that surgery could be required to correct PAH, and that this alleged failure-to-warn caused her injury, should be dismissed.

Plaintiff also alleges that Zeltiq failed to warn her physician of the "the actual incidence and occurrence of PAH following CoolSculpting." *E.g.*, Am. Compl. ¶ 137. The CoolSculpting System User Manual described PAH as a "Rare Side Effect." Plaintiff does not allege that description is inaccurate.[10] Rather, plaintiff contends that Zeltiq was required to warn her physician of the specific numerical frequency rate of PAH from CoolSculpting treatments. *E.g.*, Am. Compl. ¶ 114. But that is not the law: "courts have refused to graft onto the adequacy [of warnings] standard a requirement that a package insert must include specific adverse event frequencies." *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 405 (S.D.N.Y. 2014); *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 699 (W.D.N.Y. 2017) (agreeing that "New York law does not require drug manufacturers to include specific information regarding the frequency of adverse events"); *see also Cates*, 535 F. Supp. 3d at 1229 ("[T]here was nothing inadequate or misleading about [Zeltiq's] warning that PH was a rare side effect causing visibly enlarged tissue

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n.13 (citing Fed. R. Evid. 201). Plaintiff quotes from the Informed Consent in her Complaint. Am. Compl. ¶ 84.

[10] Plaintiff never pleads that PAH resulting from CoolSculpting is not "rare." At most, plaintiff alleges, upon information and belief, that as of her November 2021 Amended Complaint, Zeltiq "had received thousands of reports of consumers . . . developing PAH after treatment . . . ." Am. Compl. ¶ 140. Plaintiff thus pleads a vague numerator but no denominator for CoolSculpting's alleged PAH incidence rate. Plaintiff incorporates Zeltiq's 2015 Form 10-K into her complaint (*id.* ¶ 28), and that document states that as of then (now several years ago), approximately 2.5 million individual CoolSculpting treatment cycles had been sold. Zeltiq 10K at 4 (Dec. 31, 2015), https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm. Even using 19,999 as the current numerator (as plaintiff pleaded "thousands," but not "tens of thousands" of PAH reports), applying that to even a several-years-outdated denominator of 2.5 million CoolSculpting treatment cycles yields a PAH frequency rate of less than one percent (0.80%). Thus, even the most favorable interpretation of plaintiff's allegations is consistent with Zeltiq's description of PAH as "rare." *See Cates*, 535 F. Supp. 3d at 1229 ("[E]very authority cited by Plaintiff describes the frequency of PH as 'rare,' which is the same term used by Defendant's warnings.")

volume that does not go away on its own and may require surgical intervention. Accordingly, Defendant's warnings to CoolSculpting providers (*i.e.*, learned intermediaries) were adequate as a matter of law.").

Because Zeltiq warned of the precise injury plaintiff alleges she experienced, plaintiff does not state a claim that Zeltiq failed to warn.

III. If reached, counts 4, 6, 7, 8, 9 and 10 of the Amended Complaint each independently fail to state a claim.

A. Plaintiff fails to state an express-warranty claim (count 4).

Under New York law, a plaintiff bringing an express-warranty claim must allege (1) a material statement amounting to a warranty; (2) reliance on the warranty as the basis for the contract; (3) breach of the warranty; and (4) injury to the buyer caused by the breach. *Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014). Plaintiff fails to adequately plead all four elements.

On the first element—a material statement amounting to an express warranty—the only purported "warranties" that plaintiff alleges are (1) Zeltiq's description of CoolSculpting as a "safe and effective" treatment, and (2) Zeltiq's use of the phrase "No surgery. No downtime. Unmistakable results." in promotional materials. Am. Compl. ¶¶ 214, 217. Neither of these statements rises to the level of an express warranty.

An express warranty is an "affirmation of fact or promise . . . that the good shall conform to the affirmation or promise." N.Y. U.C.C. § 2-313(1)(a). This Court and others applying New York law hold that vague, general statements like "safe and effective" and "[un]mistakable results" are not factual affirmations or promises actionable as express warranties. *See Krulewich v. Covidien, LP*, 498 F. Supp. 3d 566, 578–79 (S.D.N.Y. 2020) (collecting cases and holding that statements like "safe and effective," "the most complete hernia repair solution," and "the most

studied, innovative and reliable hernia products available today" were not definite enough to be warranties); *Tears*, 344 F. Supp. 3d at 512–13 (dismissing express-warranty claims against maker of medical device based on statements like "Trusted Performance, Timeless Design," "Proven Stability," "Established Filter Performance," and "Promot[ing] Clot Lysis"). Thus, plaintiff fails to allege a legally cognizable express warranty.

On the second element—reliance—plaintiff does not adequately plead that she relied on either of these supposed warranty statements. She pleads the existence of various Zeltiq materials in which these statements appeared. *E.g.*, Am. Compl. ¶¶ 24, 25, 47, 57, 58, 59. But she does not plead whether she saw some or all of these statements, or which ones. She makes the boilerplate assertion that she "relied on ZELTIQ's express warranties of safety and efficacy, 'no surgery', and 'no downtime'" (Am. Compl. ¶ 217), but she never pleads actual facts about what she saw; she only makes the vague allegation that she "learned about the CoolSculpting System from ZELTIQ's direct-to-consumer advertisements, ZELTIQ's promotional materials, and socially among her friends." *Id.* ¶ 68. "Without the 'when, where, and how' leading to [plaintiff's] reliance . . . an express-warranty claim is too conclusory to pass muster under Rule 12(b)(6)." *Koublani v. Cochlear Ltd.*, No. 2:20-cv-1741, 2021 WL 2577068, at *15 (E.D.N.Y. June 23, 2021) (collecting cases).

On the elements of reliance and causation, even if the statements at issue were warranties (they are not), and even if plaintiff had plausibly pleaded that she saw them (she has not), she also pleads that before her first CoolSculpting treatment she was informed, understood and acknowledged that CoolSculpting treatment presented the "possibility of fat growing instead of going away," which "may require surgical correction" and that "an unexpected complication or less than desirable result can occur, which may result in the need for further treatments(s) [sic], .

. . prolonged recovery [and] loss of work time." Ex. 3, Informed Consent at 000015. Plaintiff does not plausibly plead how, given that she admits she was informed of, understood and acknowledged these risks, she could have relied on a supposed warranty that CoolSculpting was absolutely safe, guaranteed effective, and that the consequences of the treatment could never lead to the need for further procedures that might require recovery time and how that supposed reliance could have been the legal cause of her injury. To the contrary, plaintiff pleads she affirmatively disclaimed any "guaranties [sic] or warranties of any kind, either express or implied." *Id.* Her self-contradictory pleading dooms the reliance and causation elements of her express-warranty claim.

On the third element—breach of the warranty—plaintiff would fail if there were a cognizable warranty that she relied on. The FDA's Special Controls document for CoolSculpting notes that the controls "will be sufficient to provide reasonable assurance of the *safety and effectiveness* of the [CoolSculpting System]." Ex. 1, FDA Special Controls at 1 (emphasis added). Plaintiff does not plead (nor could she) that Zeltiq did not adhere to those FDA Special Controls. Thus, even if "safe and effective" were a warranty and plaintiff had adequately pleaded she relied on it, she has not adequately pleaded it was breached. *See Otero v. Zeltiq Aesthetics, Inc.*, No. CV 17-3994-DMG, 2018 WL 3012942, at *2 (C.D. Cal. June 11, 2018) (rejecting CoolSculpting consumer-protection claim alleging that "safe and effective" was misleading); *see also Perez v. B. Braun Med., Inc.*, No. 17 CIV. 8512, 2018 WL 2316334, at *6 (S.D.N.Y. May 9, 2018) ("That there are side effects associated with IVC filters that are implanted long-term, does not mean that Perez's IVC filter has not been effective for implantation into the IVC to prevent PE and DVT for which it was designed or that it is not safer

than the alternative."). And because she has not adequately pleaded breach, she does not and cannot plead an injury caused by a breach.

Additionally, regarding "no surgery" and "no downtime," these statements expressly refer to the CoolSculpting treatments themselves. Am. Compl. ¶ 24 ("*the CoolSculpting procedure* requires no surgery or downtime" (emphasis added)). Plaintiff does not plead that any of her CoolSculpting treatments themselves involved surgery. Nor does she plead that she required any downtime resulting from the CoolSculpting treatments themselves. *See, e.g.*, Am. Compl. ¶¶ 85–91. Plaintiff therefore fails to plead that these alleged warranties were breached.

B. Plaintiff fails to state any fraud-based claims (counts 6 through 9).

Plaintiff's fraud-based claims in counts 6 through 9[11] should be dismissed as inadequately pleaded. Rule 9(b) requires plaintiff to plead "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Plaintiff must specify "the who, what, when, where, and how of the fraud." *Richards v. Johnson & Johnson, Inc.*, No. 5:17-cv-00178, 2018 WL 2976002, at *7 (N.D.N.Y. June 12, 2018) (cleaned up). Each of counts 6 through 9 requires plaintiff to identify a specific misrepresentation of fact and allege with particularity the circumstances of her and her physician's reliance on those specific statements. *See Tears*, 344 F. Supp. 3d at 514–16 (explaining elements of fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation and dismissing those claims for failure to plead with particularity); *Burnett v. Halyard Health, Inc.*, No. 3:16-cv-119, 2016 WL 11746742, at *7 (N.D.N.Y. May 12, 2016) (examining a claim for "fraud and deceit" as fraud, explaining

[11] Plaintiff's count 8 is for negligent misrepresentation. The same pleading standard under Rule 9(b) applies to that claim. *E.g.*, *O'Neil v. Argon Med.*, No. 3:17-CV-640, 2020 WL 1149904, at *10 (N.D.N.Y. Feb. 13, 2020).

elements, and dismissing those claims for failure to plead with particularity). Plaintiff fails to plead those necessary specifics here.

To be sure, plaintiff pleads the contents of several random CoolSculpting promotional materials. Some of those materials obviously are not alleged to have been made to plaintiff, *see e.g.*, Am. Compl. ¶¶ 21–26 (alleging statements made in documents from Zeltiq to CoolSculpting providers), and nowhere does plaintiff plead facts to support a conclusion that her physician saw or relied on any of those materials. Three of the TV advertisements she identifies were, according to her Amended Complaint, aired only *after* her CoolSculpting treatments ended. *Compare id.* ¶ 58, bullets 2, 3, and 4 (discussing 2017, 2018, and 2020 ads), *with id.* ¶ 91 (pleading that her last CoolSculpting treatment occurred in February 2016). Plaintiff offers this scattershot of allegations and leaves Zeltiq and the Court to guess which promotional material (if any) she or her physician saw, what else the materials said, when plaintiff or her physician saw it, or why they relied on it to the exclusion of Zeltiq's express warnings. Again, the most specific plaintiff ever gets in her Amended Complaint about what she or her physician actually saw, heard, or read is when she alleges that she "learned about the CoolSculpting System from ZELTIQ's direct-to-consumer advertisements, ZELTIQ's promotional materials, and socially among her friends." *Id.* ¶ 68. That is not a particularized allegation of what statements by Zeltiq supposedly defrauded her and the where, when, and how she came to see them, much less which statements defrauded her physician and how. Conclusory, non-particularized assertions that "Ms. Evangelista and her provider relied on ZELTIQ's representations that the CoolSculpting System was safe and effective," *e.g.*, *id.* ¶¶ 252, 273, 285, 315, are also not sufficient under Rule 9(b). *See O'Neil*, 2020 WL 1149904, at *11 ("The amended complaint also is devoid of facts to support the bare assertion of the legal elements . . . that Plaintiff's healthcare providers

reasonably relied on the misrepresentations."); *Ohanian v. Apple, Inc.*, No. 20 Civ. 5162, 2021 WL 5331753, at *3–4 (S.D.N.Y. Nov. 16, 2021); *Quintana v. B. Braun Med., Inc.*, No. 17-cv-06614, 2018 WL 3559091, at *8 (S.D.N.Y. July 24, 2018).

Courts analyzing allegations comparable to plaintiff's under New York law have held that without pleading particularized facts regarding when and where particular statements were reviewed and relied on, fraud claims fail. *See, e.g.*, *Oden*, 330 F. Supp. 3d at 897–88 ("[A]lthough Plaintiff pleads that certain statements on Defendant's webpage and brochure were fraudulent, . . . these allegations . . . lack the particularized facts indicating, at the very least, where and when the statements were made or viewed by Plaintiff or his physicians and why the statements were fraudulent."); *Cosh v. Atrium Med.*, No. 1:18-cv-08335, 2020 WL 583826, at *5 (S.D.N.Y. Feb. 6, 2020) (dismissing fraud claim where complaint "lack[ed] details regarding whether and how [the plaintiff] and her physician reviewed and relied upon Defendant's statements"); *Morrison v. Hoffmann-La Roche*, No. 14-CV-4476, 2016 WL 5678546, at *9 (E.D.N.Y. Sept. 29, 2016) ("Absent allegations of fact demonstrating Plaintiff's reliance on the alleged misrepresentations, Plaintiff's fraudulent misrepresentation claim cannot stand.").

Plaintiff's fraud claims fail because she has not alleged which statements she or her physician saw, relied on, or under what circumstances they did so.

C. Plaintiff fails to state a claim for violation of N.Y. Gen. Bus. Law §§ 349 and 350 (count 10).

To state a claim under N.Y. Gen. Bus. Law §§ 349 and 350, "a plaintiff must establish that: (1) the defendant engaged in an act that was directed at consumers; (2) the act engaged in was materially deceptive or misleading; and (3) the plaintiff was injured as a result of the defendant's act." *Amos v. Biogen Idec, Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014). Plaintiff's claims fail all three elements.

First, the conduct plaintiff alleges was "deceptive or misleading"—providing warnings about adverse risks from medical procedures involving a prescription medical device—is not consumer-oriented conduct as a matter of law. *See* Am. Compl. ¶ 330. For instance, where a plaintiff brought N.Y. Gen. Bus. Law claims "alleg[ing] that the defendants deceived consumers by concealing information about the dangers of taking" a weight-loss drug, the Western District of New York dismissed that claim, finding:

> because a drug manufacturer's duty to warn of a drug's side effects runs to the doctor prescribing the drug, and not to the user of the drug, the issuance of drug warnings, for purposes of Section 349, is not an act directed at consumers, and therefore any alleged deceptive act related to the issuance of those warnings is not a 'consumer oriented' act actionable under Section 349.

Amos, 28 F. Supp. 3d at 173; *see also Wholey v. Amgen*, 86 N.Y.S.3d 16, 17–18 (App. Div. 2018) ("The claim of violation of General Business Law §§ 349 and 350 must be dismissed, because the generally alleged deceptive practice of failing to provide adequate warnings by concealing information is, as a matter of law, not a practice directed at consumers."); *Zottola* 2021 WL 4460563, at *4 (similar); *Scism v. Ethicon, Inc.*, No. 1:19-CV-1543, 2020 WL 1245349, at *8 (N.D.N.Y. Mar. 16, 2020) (similar).

Second, plaintiff has alleged no particular materially deceptive or misleading act. Plaintiff vaguely alleges that Zeltiq was deceptive in "marketing and promotion of the CoolSculpting System, including, without limitation, website, television, radio, print media, posters, office displays, and promotional brochures." Am. Compl. ¶ 333. But "in determining whether a reasonable consumer would be misled, courts view each allegedly misleading statement *in light of its context on the product label or advertisement as a whole*." *Barreto v. Westbrae Natural*, 518 F. Supp. 3d 795, 802 (S.D.N.Y. 2021) (cleaned up) (emphasis added). Plaintiff does not specify any particular allegedly deceptive statement in the N.Y. Gen. Bus. Law section of her Amended Complaint, and thus there is no way to evaluate a statement (or

omission) in context. *See Fink v. Time Warner*, 714 F.3d 739, 742 (2d Cir. 2013) (affirming dismissal of § 349 claim: "The primary evidence in a consumer-fraud case arising out of allegedly false advertising is, of course, the advertising itself. And in determining whether a reasonable consumer would have been misled by a particular advertisement, context is crucial.").

Third, even if the Court considers the general references to promotional materials throughout the Amended Complaint as the "deceptive or misleading conduct," plaintiff has not pleaded causation. "To properly allege causation, a plaintiff must state in his complaint that he has seen the misleading statements of which he complains." *Goldemberg v. Johnson & Johnson Cons. Cos.*, 8 F. Supp. 3d 467, 480 (S.D.N.Y. 2014). Plaintiff does not do that here. Instead, she pleads the existence of several CoolSculpting promotional statements—some of which were not directed to her as a consumer and some of which she expressly pleads did not exist until after she stopped receiving CoolSculpting treatment—and then just vaguely asserts that she "learned about the CoolSculpting System from ZELTIQ's direct-to-consumer advertisements, ZELTIQ's promotional materials, and socially among her friends." Am. Compl. ¶ 68. This is not enough: "Although Plaintiff sets forth certain statements contained on Defendant's website and in its product brochure, . . . these allegations neither explicitly state nor permit the plausible inference that Plaintiff actually saw these statements prior to making the determination (in conjunction with [her] physicians)" to undergo medical treatment. *Oden*, 330 F. Supp. 3d at 902; *see also Lugones v. Pete and Gerry's*, 440 F. Supp. 3d 226, 240 (S.D.N.Y. 2020) ("[N.Y. Gen. Bus. Law] claims can only be based on alleged statements and images that Plaintiffs claim to have viewed before they purchased [the product]."); *Tears*, 344 F. Supp. 3d at 516–17 (dismissing claims even where plaintiff alleged he was given a brochure but did "not suggest that the statements he identifie[d] as misleading in the brochure led to his decision to purchase the filter").

Plaintiff fails to plead any elements of her claims under N.Y. Gen. Bus. Law §§ 349 and 350; they should be dismissed.

CONCLUSION

For these reasons, the Court should dismiss:

- Plaintiff's claims for failure to warn (count 1), design defect (count 2), negligence (count 3), express warranty (count 4), implied warranty (count 5), fraudulent misrepresentation (count 6), fraudulent concealment (count 7), negligent misrepresentation (count 8), fraud and deceit (count 9), and N.Y. Gen. Bus. Law §§ 349 and 350 (count 10) as time-barred by the applicable statutes of limitations;
- The portions of plaintiff's claims for failure to warn (count 1), negligence (count 3), express warranty (count 4), implied warranty (count 5), fraudulent misrepresentation (count 6), fraudulent concealment (count 7), negligent misrepresentation (count 8), fraud and deceit (count 9), and N.Y. Gen. Bus. Law §§ 349 and 350 (count 10) that are based on Zeltiq's alleged failure to warn plaintiff of the risks associated with CoolSculpting under the learned intermediary doctrine and as preempted by federal law;
- The portions of plaintiff's claims for failure to warn (the same as above) that are based on Zeltiq's alleged failure to warn plaintiff's physician of the risk of PAH associated with CoolSculpting and that PAH may require surgery to correct; and
- Plaintiff's claims for express warranty (count 4), fraudulent misrepresentation (count 6), fraudulent concealment (count 7), negligent misrepresentation (count 8), fraud and deceit (count 9), and N.Y. Gen. Bus. Law §§ 349 and 350 (count 10) for failure to adequately plead the required elements of those claims.

Dated: December 21, 2021

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 21st day of December 2021, a true and correct copy of the foregoing was filed through the Court's CM/ECF case management system, which will send a notice of electronic filing to all counsel of record.

s/ Alyson B. Jones
Attorney